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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,023	07/11/2001	Jack R. Wands	21486-032DIV1	3871
30623	7590	12/17/2003		
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			EXAMINER	
			YU, MISOOK	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 12/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/903,023	WANDS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 26 September 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3,5-9,39,40,43,45,46,51,52 and 55-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3,5-9,39,40,43,45,46,51,52 and 55-59 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

**DETAILED ACTION**

Claims 1-3, 5-9, 39, 40, 43, 45, 46, 51, 52, and 55-59 are pending and under consideration.

***Claim Rejections - 35 USC § 112***

Claim 9 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim is drawn to method for prognosis by detecting HAAH in a bodily fluid. Applicant argues with data presented in Dr. Lebowitz's declaration filed on 9-26-2003 that HAAH is found in bodily fluid of many different cancer patients. However, neither the specification nor the data in the declaration teaches any correlation between tumor stage and HAAH in a bodily fluid in a bodily fluid. Wer-Remers et al (The American Journal of Gastroenterology, 1997, pages 790-794) teach that tumor prognosis using a tumor marker expressed in tissue and/or present in bodily fluid is unpredictable and require actual experiments. Note Table 3 at page 793.

Claims 7, 8, 40, 45, 55, 56, and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims recite specific hybridoma producing

monoclonal antibodies. This rejection is maintained because the deposit appears to be made **after the effective filing date of the application** for patent in the United States. A verified statement is required from a person in a position to corroborate that the biological material described in the specification as filed is the same as that deposited in the depository, stating that the deposited material is identical to the biological material described in the specification and was in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

***Claim Rejections - 35 USC § 102***

The rejection of claim 45 under 35 U.S.C. **102(b)** as being anticipated by Lavaissiere et al (IDS C19, 1996, J. Clin. Invest. 98, pages 1313-1323) **is withdrawn** because the claims recite specific hybridomas and the art of record do not disclose the specific hybridoma..

***Claim Rejections - 35 USC § 103***

The indicated allowability of claim 57 is withdrawn in view on careful reconsideration of tumor marker in general in the current state of art.

Claims 1-3, 5-7, 40, 43, 46, 51, 52, 57, 58, and 59 rejected under 35 U.S.C. 103(a) as being unpatentable over De la Monte et al (IDS 34, 01-1999, Modern Pathology 12:170A) and Lavaissiere et al (IDS C19, 1996, J. Clin. Invest. 98, pages

1313-1323) and further in view of Wer-Remers et al (The American Journal of Gastroenterology, 1997, pages 790-794).

The claims are interpreted as drawn to cancer diagnosis by detecting HAAH in bodily fluid by immunohistochemistry (all the claims except claim 57) and diagnosing pancreatic cancer (claim 57) by detecting HAAH in bodily tissue. De la Monte et al teach HAAH protein overexpression in CNS cancers and Lavaissiere et al teach overexpression of HAAH in HCC. Teachings of Lavaissiere et al and De la Monte et al suggest that the HAAH overexpression is not limited to a specific tumor or tumor with specific tissue origin but could be applied to many diverse tumors such as CNS and HCC. As for detecting a tumor marker over-expressed in tissue, Wer-Remers et al teach one skilled in the art tests whether a tumor over-expressed could be detected in bodily fluid, thus providing motivation to one in ordinary skill to look for bodily fluid overexpression of a cancer marker because detecting a cancer biomarker in bodily fluid such as serum would be much less invasive than biopsy of brain, for example.

Since the primary references teach that HAAH could be overexpressed in many tumors and also teach all the necessary reagents for such detection, and secondary reference teach tissue expression and bodily expression is correlated for a certain tumor biomarker in, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to arrive at instant invention with reasonable expectation of success.

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over De la Monte et al (IDS 34, 01-1999, Modern Pathology 12:170A) and Lavaissiere et al (IDS

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C19, 1996, J. Clin. Invest. 98, pages 1313-1323) in view of Wer-Remers et al (The American Journal of Gastroenterology, 1997, pages 790-794) as applied to claim 1 above and further in view of Wer-Remers et al (The American Journal of Gastroenterology, 1997, pages 790-794) further in view of Huse (1992, Antibody Engineering, Borrebaeck C ed., page 103-107 only).

The claim is drawn to method of base claim 1 using a single chain antibody.

Huse teaches making a single chain antibody from an antibody specific for a known antigen is a routine procedure in the art and one in ordinary skill knows generating a single chain Fv antibody against a useful antigen is cost-effective because it takes less time to purify the antibody. A single chain antibody is another variation of the primary reference that one in ordinary skill could do with reasonable expectation of success.

### ***Conclusion***

All other rejections and/or objections not repeated in this Office action is withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Misook Yu whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

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305-3014 for regular communications and 703-872-9307 for After Final  
communications.

Any inquiry of a general nature or relating to the status of this application or  
proceeding should be directed to the receptionist whose telephone number is 703-308-  
0196.

Misook Yu

December 15, 2003

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Misook Yu  
December 15, 2003